IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and FOOD AND DRUG ADMINISTRATION,

Defendants.
_____/

No. C 07-01049 WHA

**ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND**

## INTRODUCTION

In this action under the Administrative Procedure Act, plaintiff Americans for Safe Access seeks to compel the US Department of Health and Human Service to correct statements that marijuana has no currently accepted medical use. Defendants' motion to dismiss plaintiff's claim pursuant to Rule 12(b)(6) is **GRANTED**. Plaintiff is granted leave to amend, however, with regard to whether defendants should be required to make a substantive response to plaintiff's information-correction petition.

## STATEMENT

The Information Quality Act (IQA), also known as the Data Quality Act, provides that:

> The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 [this section] of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for

> ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code [this chapter], commonly referred to as the Paperwork Reduction Act.

Pub. L. No. 106–554, § 1(a)(3) [Title V, § 515](Dec. 21, 2000) (published at 44 U.S.C. 3516 note). In furtherance of the goals of the statute, the IQA requires federal agencies to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines [of quality, objectivity, utility, and integrity of information]." *Ibid*.

Pursuant to the IQA, HHS has established administrative petition and review mechanisms by which parties can address their grievances. *See* United States Department of Health and Human Services, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, *http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml*.[*] The HHS guidelines provide for both an initial petition and an administrative appeal:

> Based on a review of the information provided, the agency will determine whether a correction is warranted and if, so what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction. The response will describe how the complainant may request reconsideration. The agency will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date . . . .
>
> If the individual submitting the complaint does not agree with the agency's decision (including the corrective action), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it,

[*] These guidelines are only published on the HHS website; they do not appear in the Code of Federal Regulations.

> clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.
>
> The agency official who handles the original complaint will not have responsibility for resolving the appeal. The agency will respond to all requests for appeals within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date.

*Ibid*.

This action revolves around ongoing federal dissemination of information stating that marijuana lacks currently accepted medical use. Plaintiff Americans for Safe Access (ASA) is an advocacy organization, based in Oakland, which promotes increased access to medical marijuana. In October of 2004, ASA filed an IQA information-correction petition with HHS, asking that HHS revise and "correct" information it disseminated about medical marijuana. Specifically, ASA requested that four statements in a letter from the Surgeon General to the DEA Administrator, which were published in the Federal Register, be revised. These statements all generally suggested that marijuana "has no currently accepted medical use in the United States" (Compl. ¶ 16).

After some interim responses, in which HHS extended the time for review far longer than 60 days in order to consult with the Drug Enforcement Administration, HHS responded to plaintiff's petition on April 20, 2005. The response referred to the DEA's ongoing review of a separate marijuana-rescheduling petition under the Controlled Substances Act which had been pending since October 2002. This second petition was filed by the Coalition for Rescheduling Cannabis, an association of advocacy groups including plaintiff's organization. HHS said that "in the course of this [rescheduling] review, HHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana" (Br. at 10). HHS therefore refused to either grant or deny plaintiff's petition.

Plaintiff filed a request for reconsideration with HHS on May 19, 2005, arguing that HHS was evading its data-quality responsibilities and delaying a response in contravention of its guidelines. HHS responded to this administrative appeal on July 12, 2006. The response did not

address plaintiff's purported scientific evidence and did not explicitly grant or deny plaintiff's petition. HHS did say, however, that it hoped to provide a response by September 2006 to the separate marijuana-rescheduling petition under the Controlled Substances Act. Although plaintiff had argued that "the CSA [rescheduling] process should not be utilized because of the length of time it involves," HHS responded that "a comprehensive review is essential to ensure that our recommendation [to DEA] is accurate" (Br. at 11). Plaintiff alleges in its complaint that HHS has still not responded to the separate marijuana-rescheduling petition. Plaintiff filed the present suit for declaratory and injunctive relief under the Administrative Procedure Act on February 21, 2007 (Compl. ¶ 15–22). This court has subject-matter jurisdiction because plaintiff presents a federal question pursuant to 28 U.S.C. 1331 and 1361.

## ANALYSIS

The APA allows judicial review of federal agency action that is either "made reviewable by statute [or] final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. This order holds that the IQA does not subject agency IQA decisions to judicial review. Nor is there any final agency action on the present record.

### 1. AGENCY FACT DETERMINATIONS ARE NOT JUDICIALLY REVIEWABLE UNDER THE IQA.

Although the Ninth Circuit has not addressed the issue, courts in other circuits have unanimously and persuasively rejected a right of judicial review under the Information Quality Act. True, the IQA directed the Office of Management and Budget to issue guidelines that provide "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." Pub. L. No. 106–554, § 1(a)(3) [Title V, § 515]. The IQA, however, contained no provisions permitting judicial review of the information disseminated by agencies. Instead, the Act stated that the OMB must "establish *administrative mechanisms* allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued." *Ibid*. (emphasis added).

In the *Salt Institute* decision, a salt trade association brought suit under the IQA to correct and obtain data supporting the National Heart, Lung and Blood Institute's dissemination of data on the link between sodium intake and high blood pressure. The Fourth Circuit affirmed the district court's dismissal of the suit, stating that "the IQA . . . does not create any legal right to information or its correctness." *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006). Without the existence of a legal right, the Fourth Circuit held that the plaintiff "failed to establish an injury in fact sufficient to satisfy Article III." *Ibid*. The only remedy for IQA claims, therefore, was held to be in the administrative process provided by the statute: "[t]he language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004) (Lee, J.).

The only other federal court to consider an IQA claim also dismissed the suit due to lack of a right to judicial review. *In re Operation of the Missouri River System Litigation*, 363 F. Supp. 2d 1145, 1174 (D. Minn. 2004) (Magnuson, J.), *vacated in part and aff'd in part on other grounds*, 421 F.3d 618 (8th Cir. 2005), held that the IQA provided no meaningful standard of review for APA claims. *Missouri River* held that although the IQA requires the OMB to issue guidelines that ensure the "quality, objectivity, utility, and integrity" of information disseminated by the government, "the plain language of the legislation fails to define these terms." *Id*. at 1174–75. Additionally, since "the history of the legislation fails to provide any indication of the scope of these terms," and "absent any 'meaningful standard' against which to evaluate the agency's discretion," the court held Congress did not intend to permit judicial review of IQA information correction requests. Instead, *Missouri River* concluded that since the IQA was "drawn in such broad terms," "there is no law to apply," and the "agency action is committed to agency discretion." *Ibid*.

The Ninth Circuit has not yet addressed the question. But the decisions from the Fourth Circuit and the District of Minnesota are persuasive. The IQA provided only an administrative remedy. Plaintiff would distinguish the *Salt Institute* decision as "decided the

way it was because the corporate plaintiff in that case was seeking to *obtain* information . . . under the IQA, not [to] *correct* erroneous information" (Opp. 24). A quick reading of the *Salt Institute* decision shows that the plaintiff there was attempting both to *obtain* and *correct* information. The *Salt Institute* plaintiff took issue with the government's publication of findings that *all* Americans, rather than just some subgroups, could reduce their blood pressure by lessening their sodium consumption. Seeking to show that this relationship only occurred in certain groups of Americans, the plaintiff in *Salt Institute* sought for the government to publicize the raw data that supported the government's findings.

**2. FINAL AGENCY ACTION IS LACKING.**

Plaintiff's other avenue for suit under the APA would be if defendants' denial of plaintiff's information quality appeals constituted final agency action. Agency action is defined under the APA as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. 551. In order for an agency action to be final, two conditions must be met. "First, the action must mark the consummation of the agency's decision-making process — it must not be of a merely tentative or interlocutory nature." *Nippon Miniature Bearing Corp. v. Weise*, 230 F.3d 1131, 1137 (9th Cir. 2000). Second, the agency action "must be one by which rights or obligations have been determined, or from which legal consequences flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal citations and quotations omitted).

Neither requirement is satisfied. Plaintiff here challenges an alleged abuse of discretion in defendants' response to plaintiff's administrative appeals under the IQA. The agency, however, has not yet passed on the merits of the information-correction petition, so the agency process has not yet run its course. Plaintiff also fails to plead the second requirement of final agency action by failing to allege any facts that suggest that defendants' failure to correct their allegedly erroneous statements has any legal consequences, or that it determines any rights or obligations. Plaintiff argues that "the legal consequence of HHS's final decision denying ASA's [p]etition and appeal is that ASA has been deprived of its right under the IQA to seek and obtain the timely correction of incorrect information" (Opp. 20). As discussed, however, plaintiff has

failed to plead that the IQA grants any legal right to the correction of information. Plaintiff has identified no other legal consequences flowing from defendants' response to their IQA information correction request. Plaintiff has therefore failed to plead that defendants' response to their administrative appeal constituted final agency action. Since leave to amend shall be granted, perhaps the new pleadings will cure these shortfalls.

**3. LEAVE TO AMEND IS WARRANTED.**

At oral argument, plaintiff discussed a potential claim under 5 U.S.C. 706(1), for defendants' failure to respond in a timely manner and on the merits of their IQA petition. Plaintiff also raised this issue in a motion for summary judgment, arguing that "[defendants] cannot shrug off ASA's IQA Petition in this manner." Plaintiff suggested in the summary judgment brief that HHS neglected to follow its IQA guidelines, which require it to respond to information correction petitions in a substantive fashion within 60 days. In the summary judgment motion, plaintiff also alleges that HHS failed to meet its IQA responsibilities of making a substantive response by "lumping together ASA's narrow request for correction of information under the IQA with [the medical marijuana rescheduling petition,] a distinct, farther-reaching and much slower process."

Under the APA, a private party can bring suit to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). Plaintiff, however, did not address the issue of defendants' "nonsubstantive" and delayed response to the IQA petition in the complaint. In the complaint, plaintiff raises a claim only under a different section of the APA, 5 U.S.C. 706(2)(A)&(C), alleging that defendants' response to their petition constituted final agency action in violation of the IQA. Plaintiff will be given leave to amend the complaint to raise the issue of whether defendant agencies violated a legal duty by not making a timely and substantive response to plaintiff's petition on its merits. Conceivably, a district court may order an agency to act on the merits of an information-correction petition within a specific time frame.

**CONCLUSION**

Plaintiff fails to identify a right to judicial review under the APA for denials of IQA information correction requests. Plaintiff therefore fails to state a claim upon which relief can be

granted. Defendants' motion to dismiss is hereby **GRANTED**. Plaintiff, however, will be given leave to amend to proceed on a theory that defendants unlawfully withheld or delayed agency action by not giving a substantive response to plaintiff's petition. Any amended complaint must be filed by **AUGUST 17, 2007**.

**IT IS SO ORDERED.**

Dated: July 24, 2007.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE